

(21) Application No 8224268
(22) Date of filing 24 Aug 1982
(43) Application published
14 Mar 1984
(51) INT CL³
A61K 9/02
(52) Domestic classification
A5B 170 190 26Y 343 34Y
351 35Y 402 40Y J
U1S 1328 A5B
(56) Documents cited
None
(58) Field of search
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(54) **Lubricating suppository**
(57) A suppository for the vaginal
canal, solid at normal ambient
temperatures but which melts at body
temperature to form a homogeneous
liquid having the appearances of a
single liquid phase comprises:
 (a) a continuous phase of a water-
 soluble polyoxyalkylene polyol
 component consisting of
 polyoxyethylene glycol of molecular
 weight from 400 to 5000, the component
 being formulated to have a melting
 range low enough for the formation of a
 clear molten liquid at less the 75°C;
 (b) from 10 to 60 parts per 100 (based
 on the weight of polyol) of a non-ionic
 surfactant of HLB value greater than 12,
 the surfactant being uniformly
 distributed through the continuous
 phase;
 (c) from 10 to 40 parts per 100 (based
 on the weight polyol), of a glyceride of an
 aliphatic carboxylic acid, distributed
 throughout the continuous phase with
 the aid of the non-ionic surfactant.

SPECIFICATION

Lubricating suppository production and use thereof

5 This invention relates to a lubricating suppository, the production and use thereof; more particularly it relates to a lubricant which is intended specifically for the human vagina.

One aspect of the present invention relates to a 10 pre-coital lubricant in suppository form. Another aspect of the present invention relates to a method for lubricating the human vagina by insertion of a solid suppository which melts to form a lubricant at human body temperature. A further aspect of the present 15 invention relates to a process for producing a lubricating suppository from a plurality of generally solid materials, at least one of which is lubricious at normal ambient temperatures.

A variety of materials have been suggested as 20 lubricants for human body canals, particularly the vaginal and anal canals. The requirements of such lubricants vary depending upon the reason for lubricating the inside surfaces of the canal. Prior to or during coitus, the human body itself provides some 25 natural lubrication. However, there is a well-established market for materials which supplement the function of the natural lubricant.

Theoretically, various lubricious materials which are not harmful to skin could be a pre-coital lubricant, 30 and petroleum jelly, mineral or triglyceride oils and similar biologically-inert oleophilic materials have been used for this purpose. Like oleophilic materials, however, they are capable of staining fabric, are relatively incompatible with natural vaginal moisture 35 and may resist removal from the skin or the interior of the vaginal canal when plain water rinses are used. Accordingly, the pharmaceutical, cosmetic and personal care industries have made efforts to formulate lubricants which are better suited for pre-coital use 40 and other vaginal canal lubricating purposes. A composition known as "K Y Jelly" is an example of a sterile, general purpose lubricant with label instructions for use as a lubricant in obstetrical and gynecological procedures and to aid in the insertion of 45 thermometers and other instruments in the vagina or rectum. "Ortho Personal Lubricant", on the other hand, is an example of a composition labelled for use specifically for sexual intercourse. Nevertheless, the latter product is somewhat similar in its composition 50 to the sterile general purpose jelly. Both products contain a major amount of water combined with a cellulose derivative and are packaged in collapsible tubes. The predominantly aqueous nature of these products may provide advantages over oleaginous 55 materials for the above reason, but, because the water component of both of these formulations appears to play an important role in making the product lubricious, upon evaporation, the lubricity may be lost. Such evaporation may occur even during coitus.

60 When insertion of a material into a human body canal (particularly the vagina or anus) is desirable, suppositories have advantages and are often preferred by patients, doctors and other users. The suppository art is a highly developed one, particularly with 65 respect to suppositories which provide a matrix for

releasing some medicament. Such suppositories may be made lubricious; see, for example, U.S. Patent No. 3,776,001. Medicators and tampons, for example have also to be made lubricious, at least on the surfaces

70 thereof. The following references are believed to be representative of this art: U.S. Patent Nos. 3,756,238; 3,815,600; 3,884,233; 3,886,940; 4,026,292; and 4,140,756.

It has now been found that a pre-coital lubricant may

75 be formulated such that it is suitable for formation into suppositories and is not dependent upon a high water content or moisture to be lubricious, but yet is water-washable to a far greater degree than the common oleaginous lubricants. Indeed, the present

80 lubricants have a high level of compatibility with plain water and may easily be solvated or uniformly distributed (dissolved and/or dispersed and/or suspended) in water. Suppositories in accordance with the present invention are solid at normal ambient

85 temperatures, but melt at human body temperature to form a substantially homogeneous liquid having the appearance of a single liquid phase, even though a glyceride of an aliphatic carboxylic acid is distributed through this homogeneous liquid. In either the liquid

90 or the solid state, the present suppositories comprise:

(a) a continuous phase comprising a polyoxyalkylene polyol component consisting essentially of polyethylene glycols having a molecular weight of from 400 to 5,000, so that this component will have a

95 melting range low enough for the present purposes;

(b) from 10 to 60 parts, per 100 parts, by weight, of the above polyol component, (typically from 10 to 30%, by weight, of the suppository), of a non-ionic surfactant having an HLB value of greater than 12

100 (typically this surfactant dissolves in the above polyol component); and

(c) from 10 to 40 parts, per 100 parts, based on the weight of the above polyol component, of a glyceride (preferably a triglyceride) of an aliphatic carboxylic

105 acid, which glyceride is uniformly distributed throughout the continuous phase with the aid of the non-ionic surfactant.

The human vagina may be pre-coitally lubricated using such a suppository by inserting the solid

110 suppository and permitting it to melt within the vaginal canal prior to coitus. The melting is generally complete within a very few minutes. If desired the insertion may take place up to a few hours before coitus.

115 Suppositories in accordance with the present invention are made by melting the polyethylene glycols at a moderately elevated temperature, thereby obtaining a homogeneous melt. The preferred non-ionic surfactant (including surfactant combinations) may be

120 dissolved in the melt. The resulting hot mixture is a suitable medium for distributing the glyceride, which is the primary lubricating substance. When a suitable blend has been formed, it may be cast into the form of suppositories using moulds or a suppository packaging material that serves as both mould and package.

As will be apparent from the foregoing, the present invention is directed specifically to the requirements of pre-coital lubrication, although the present suppositories may incidentally facilitate insertion of, for

130 example, medical instruments into human body

canals. For coital lubrication, compatibility with water or moisture is desirable not only to provide water washability, but also to facilitate combination with natural vaginal moisture and uniform spreading over all the surfaces of the vaginal canal. A relatively low viscosity in the molten state also improves the pre-coital lubricating function in accordance with the present invention. Such low viscosity may have one drawback, however: the lubricant may easily pass from the vaginal canal onto clothing or other fabric. To overcome this drawback, it has been found that an extremely high level of water compatibility may be provided without losing the other advantages of the present invention. A solid residue or stain (e.g. on fabric) from such leakage may be removed with plain water because of the extraordinarily high level of dispersion of the oleaginous phase or phases of the lubricant and the compatibility of the non-ionic surfactants with the polyoxyethylene glycol base.

Compositions in accordance with the present invention need not and preferably do not contain solid material which will not readily disperse or become suspended in water. Even the prior art cellulosic materials are more difficult to suspend or disperse in water than the present compositions. The polyoxyalkylene polyol component, since it consists essentially of polyethylene glycols, is essentially soluble in water. The non-ionic surfactant component is essentially soluble in the polyethylene glycols, thereby simplifying the phase relationship between the glycols and the glyceride lubricant. The concentration of non-ionic surfactant is sufficiently high to ensure that the glyceride will be well emulsified and may be re-emulsified if a spot or stain on fabric results from the application of the present invention.

Even in the absence of natural vaginal moisture, a fully or partially melted suppository or vaginal insert in accordance with the present invention has lubricating properties. The present unique combination of ingredients further allows the melted lubricating substance to become miscible with the vaginal moisture present even in small amounts. As the insert or suppository melts and mixes with any vaginal moisture, it spreads readily throughout the vagina. In addition, the lubricity provided by the present invention is not reduced due to evaporation of moisture during coitus.

In addition to the glycol, glyceride lubricant and surfactant components of the present composition, it may be further modified by a lower aliphatic monomeric hydrophilic polyol which will dissolve in the glycol phase. A preferred monomeric polyol is glycerin. Pigments, fillers, extenders, preservatives and antioxidants may also be included in the composition, but it is generally preferred to avoid the use of fillers, extenders, or pigments which will leave a visible solid residue. For antioxidant or preservative effects, various FDA-approved compounds are suitable, including the conventional alkylated hydroaromatic compounds, such as BHT (butylated hydroxytoluene) or BHA (butylated hydroxyanisole).

The major amount of the continuous phase comprises one or more (preferably a blend) of polyoxyethylene or polyethylene glycols. These glycols contain an oxyethylene chain having an extraordinary

compatibility with water and a hydroscopicity of at least 0.1%, preferably at least 1% of glycerin. Because these polyethylene glycols comprise such a large proportion of the lubricating suppository, it is preferred that a single such glycol (if used alone) or a combination of such glycols be solid at normal ambient temperatures (from 20 to 25°C) and preferably at moderately elevated temperatures which may inadvertently be reached during storage, e.g. 30 or 35°C. On the other hand, it is desirable that the glycol component be capable of melting at temperatures close to human body temperature (e.g. 37°C). The melting point of the glycol component may of course, be depressed by blending with compatible liquids or low-melting solids. Nevertheless, it is preferable that, in the absence of such liquids or low-melting solids, the glycol component have a melting point or melting range sufficiently low to ensure the formation of a clear molten liquid at less than 75°C., more preferably at less than 55 or 60°C. Among the low-melting solids and liquids which may provide the melting point depressant effect are low molecular weight polyoxyethylene glycols which are available in molecular weights well below 1,000 (equivalent weights well below 500). It is preferred, however, to keep the molecular weight of the lowest-melting glycol above 400. A polyethylene glycol having an average molecular weight of about 500 could be a solid at 20°C, but may have the consistency of low-melting petrolatum.

Polyoxyethylene glycols are available in molecular weights above 1,000,000, but most of the molecular weight range above 5,000 is of limited utility for the present purposes because of the relatively high melting points or solidification ranges of such materials. The optimum average molecular weight range for glycols useful in accordance with the present invention is above 900 and below 2,000, thereby ensuring a solidification range below 60°C. A blend of such glycols within this molecular weight range will generally begin to melt at temperatures no higher than 50°C. With "fine tuning" of the blend, it may be formulated to begin to melt at 36-38 or 39°C, which is approximately the ideal melting range, absent a melting point depressant other than a low molecular weight polyoxyethylene glycol. With a melting point depressant this range may be extended to 40°C or higher, as explained above. In any event, it is desirable that the glycol component begin to melt at 36-38°C within a few minutes.

A particularly effective way to provide the water-washability of lubricating compositions in accordance with the present invention is to ensure that the glyceride (e.g. the glyceryl trialkanoate) is well distributed with a surfactant component which is compatible with the polyethylene glycols in the continuous phase and, perhaps equally important, that these glycols have a measurable degree of water solubility, e.g. more than 10%, by weight. A remarkable feature of the polyethylene glycols is that even relatively high polymers of ethylene oxide have water solubility. At relatively low molecular weights, these hydroxy-terminated polymers will dissolve to the extent of about 70%, by weight, (or more) in water. As the molecular weight increases into the thousands, the water solubility declines, but not drastically.

Polyoxyethylene glycols used in accordance with the present invention, either individually or in combination, typically have a water solubility in excess of 50% on a weight/weight basis. For this reason, mixtures of 5 oxyethylene polymers with oxypropylene or tetramethyleneoxy polymers are not preferred. Among nonionic polymers, it is difficult to improve upon the water solubility of the oxyethylene (i.e. ethylene oxide) polymers, and certainly the water compatibility 10 of propylene oxide or other oxyalkylene polymers is meagre in comparison to the polyoxyethylenes. In short, the oxyalkylene chains obtained from two-carbon oxyalkylene units are unique among this class of structures, particularly in terms of the compatibility 15 with water thereof. Absent modification with pendant or recurring oxyethylene units, other hydrophilic solids, such as cellulose, also lack this extraordinarily high degree of water compatibility. Relatively hydrophobic or oleophilic compounds which may detract 20 from the water compatibility of the present glycol component are preferably excluded from this component. With the exception of very minor amounts of antioxidants and preservatives, for example, it will generally be the case that the least hydrophilic 25 ingredient of the composition in accordance with the present invention will be the glyceride, which is substantially insoluble in water.

In typical suppository compositions in accordance with the present invention, from 50 to 70%, by 30 weight, of the composition is this glycol component. The total composition contains a non-ionic surfactant component which may be uniformly distributed (dissolved, dispersed or suspended) through the continuous phase. It is generally preferred that this 35 surfactant component be sufficiently compatible with the continuous phase to form a part of it, thereby simplifying the phase relationships within the composition. It is also preferred that the surfactant have a significant degree of compatibility with water, which 40 may be provided by selecting surfactant compounds or compositions having an HLB value of greater than 12, more preferably greater than 14. (The HLB value is the "hydrophile-lipophile balance" and is determined in accordance with well known procedures published 45 in the scientific and trade literature; HLB values of below 9 are considered generally lipophilic, values of 9-11 are considered intermediate or borderline and value of about 12 are clearly hydrophilic.) Although 50 HLB values of 20 or 30 or more have been reported, it is generally unnecessary to use non-ionic surfactants having values significantly above 18. When a combination of surfactants is used (as is particularly preferred in accordance with the present invention), the overall HLB value may be determined on a 55 weighted-average basis, as conventional in the detergent art. Some non-ionic emulsifiers and other surfactants will actually dissolve in molten polyoxyethylene glycols, foremost among these surfactants being those containing oxyethylene chains, such as 60 the poly(oxyethylene) polyol esters, poly(oxyethylene) polyol ethers and mixtures of these esters and ethers. Some of these compounds, such as polyoxyethylene (20) sorbitan mono-oleate, are also water-soluble. Several series of polyoxyethylene 65 ethers of higher aliphatic alcohols are commercially

available, as are the polyoxyethylene derivatives of higher aliphatic carboxylic acids, e.g. the polyoxyethylene polyol alcanoates. Unsaturated aliphatic carboxylic acids and alcohols may also be used to 70 form the desired polyoxyethylene derivatives. A significant degree of higher aliphatic character may be obtained with acids and alcohols containing at least 6 carbon atoms, preferably at least 10 carbon atoms. At C₂₈ and higher, the aliphatic character may 75 become excessive and may even be somewhat excessive at C₂₀ or C₂₂. Relatively hydrophilic nuclei, such as sorbitan and other lower aliphatic monomeric polyols, may help to counterbalance the aliphatic character of carbon chains in the C₁₂ - C₂₀ 80 range. An example of a thus-balanced compound is polyoxyethylene (20) sorbitan mono-oleate.

There may be distinct advantages in adding a lower aliphatic monomeric hydrophilic polyol to the continuous phase. Glycerin, for example, is of interest 85 because of its extraordinary affinity for water, from 10 to 100 times as much hygroscopicity as the preferred polyoxyethylene glycols. Glycerin, in fact, is commonly used as a humectant, as well as a solvent, a plasticizer and an emollient. It is a common ingredient 90 of anal suppositories and is considered safe and effective for a variety of medical uses. (Surfactants generally used in accordance with the present invention are also considered to be safe materials, the particularly preferred ones having been cleared 95 for food or drug use.) Although glycerin is an optional ingredient in the present suppositories, it is generally preferred to include from 5 to 20%, by weight, based on the total weight of the suppository composition of this compound.

100 The most important ingredient of the phase which is emulsified in the continuous phase is a lubricious glyceride, preferably a triglyceride generally considered to be safe and effective for lubricating or plasticizing human skin. The glyceryl lower alkanoates, such as triacetin and tributyrin, tend to be high 105 boiling liquids which may have plasticizing properties, but are less effective as lubricants as compared to triglycerides of the aliphatic carboxylic acids having 6 or more carbon atoms. Some of the most 110 preferred lubricants for skin are of coconut origin and contain triglycerides of C₆ - C₁₈ carboxylic acids, particularly the saturated aliphatic acids (e.g. capric, caprylic, lauric, palmitic and stearic acids). These triglycerides may be fractionated to shift the content 115 toward either the C₆ - C₁₂ triglycerides or the C₁₂ - C₁₈ triglycerides, as may be desired. Unfortunately, all of these triglycerides are substantially insoluble in water. Even glyceryl tributyrate (the C₄ analogue of the coconut-origin triglycerides) is reported to have a 120 solubility in water of only 0.01%. However, the highly effective emulsifier of surfactant component in accordance with the present invention provides excellent water washability and the prospect of virtually total removal of triglyceride residue from 125 clothing or other fabric with an essentially plain water rinse. In addition, this emulsifier system helps to provide a clear, apparently homogeneous melt within and above the melting range of the present suppository. Although the present invention is not to be 130 regarded as bound by a theory, it is believed that the

triglyceride is extremely well dispersed in the composition to the point where the composition approaches the nature of a true solution.

The oxyethylene glycols are normally the first ingredients charged to a heated mixer since they normally comprise the major amount of the suppository composition. The temperature within the mixer is maintained at a sufficiently high level to maintain the glycols in the molten state without approaching the flash point of any component of the composition. Ordinarily, it is not necessary to exceed a temperature of about 75°C in the mixer. The glycols form a clear melt, to which the non-ionic surfactant system may be added, and preferably, dissolved with stirring. The glyceride is also added under constant stirring and from 15 to 20 minutes will typically be a sufficient period of agitation thoroughly to disperse or suspend this component. The result will be a uniform distribution of all components of the composition. The glycerin or other hydrophilic polyol may be added to the composition at a suitable stage during production.

The heated mass may be poured from the mixer into moulds, demoulded and then individually wrapped in foil/laminate packaging material. Cooling of the mould is particularly desired for the purpose of obtaining rapid and complete solidification of the portion of molten material which has been poured into the mould. Alternatively, the heated mass may be cast into a preformed suppository packaging material that serves as both mould and package.

The preferred method of use is to insert the suppository into the vagina at least 5 minutes prior to sexual intercourse. If this procedure is not convenient the suppository may be inserted as much as an hour or two before intercourse and a sufficient amount of liquid lubricant will still be present in the vaginal canal when intercourse is commenced. After thorough melting of the suppository, leakage of the molten lubricant from the vaginal canal will not vitiate the effectiveness of the present invention, because of the compatibility of the triglyceride with natural lubricants, the ease of blending of the lubricant with natural moisture which may be present, the spreading of the lubricant throughout the canal and the effectiveness of very small residual amounts of the lubricant.

The present invention is illustrated by the following Example.

50 Example

A solid suppository was cast from the following formulation.

Ingredient	Parts, by Weight
Polyethylene glycol, average molecular weight 1300-1600, solidifying range 40-50°C, soft, white waxy solid, solubility in water at 20°C, approximately 70% (weight/weight), pH of a 5% aqueous solution about 6.5 (CARBONWAX (Registered Trade Mark) 1540)	25
Polyethylene glycol, average molecular weight 950-1050,	25

70	Glycerin	10
75	Polyoxyethylene (23) lauryl ether (BRIJ 35)	10
80	Polyoxyethylene (20) sorbitan mono-oleate (TWEEN (Registered Trade Mark) 80)	5*
85	Polyoxyethylene (40) stearate (MYRJ 52-5)	5
	Fractionated triglyceride of coconut origin (caprylic/capric triglyceride NEOBEE M-5)	20

* Alternatively, may be replaced with more BRIJ or MYRJ.

The HLB value of the polyoxyethylene lauryl ether and the polyoxyethylene stearate is normally within the range of from 16.5 to 17. The HLB value of the polyoxyethylene sorbitan mono-oleate is normally 15. Accordingly, the average HLB value of the non-ionic surfactant system in accordance with the present invention is above 16. The glycol component was melted and maintained within the temperature range of from 55-70°C during production of the suppository compositions. Production was carried out on a batch basis, but it may also be done

100 continuously.

1 part of antioxidant, BHT (butylated hydroxy toluene) was added to 10,000 parts of the above described composition. A suppository cast from this composition was 30 mm in length and 13 mm wide at 105 its widest point. (Suppositories from 10 to 50 mm in length and from 2 to 20 mm in width may easily be cast and moulded.)

Although not generally preferred, medicaments related to coitus, such as spermicides and bactericides may be added to suppository compositions in accordance with the present invention.

Throughout this specification, the terms "polyethylene glycol" and "polyoxyethylene glycol" are used synonymously.

115 CLAIMS:

1. A lubricating suppository for the human vaginal canal, which suppository is solid at normal ambient temperatures, but melts at human body temperature to form a substantially homogeneous liquid having 120 the appearance of a single liquid phase, which comprises:
 - (a) a continuous phase comprising a water-soluble polyoxyalkylene polyol component consisting essentially of polyoxyethylene glycol having a molecular weight of from 400 to 5000, the said component being formulated to have a melting range sufficiently low to ensure the formation of a clear molten liquid at less than 75°C;
 - (b) from 10 to 60 parts per 100 based on the weight 130 of the said polyoxyalkylene polyol component, of a

non-ionic surfactant having an HLB value of greater than 12, the said non-ionic surfactant being uniformly distributed through the said continuous phase;

(c) from 10 to 40 parts per 100 based on the weight of the said polyoxyalkylene polyol component, of a glyceride of an aliphatic carboxylic acid, the said glyceride being uniformly distributed throughout the said continuous phase with the aid of the said non-ionic surfactant; the said lubricating suppository; in either the solid or molten state, having sufficient compatibility with water to be readily uniformly distributable in water.

2. A suppository as claimed in claim 1 wherein the said continuous phase further comprises a lower aliphatic monomeric hydrophilic polyol dissolved in the said continuous phase.

3. A suppository as claimed in claim 2 wherein the said hydrophilic polyol is glycerin.

4. A suppository as claimed in any of claims 1 to 3 wherein the said non-ionic surfactant comprises a blend of oxyethylene chain-containing ester or ethers, the said blend having an HLB value of above 14, the ester or ether functional groups of the said esters or ethers comprising a higher aliphatic residue.

5. A suppository as claimed in claim 4 wherein the said HLB value is less than 18.

6. A suppository as claimed in any of claims 1 to 5 comprising:

(a) from 50 to 70%, by weight, of a blend of polyoxyethylene glycols having a molecular weight of from 900 to 2000, which blend at least begins to melt at temperatures of no higher than 50°C;

(b) dispersed in the said blend of polyoxyethylene glycols, from 10 to 20%, by weight, of a triglyceride of C₆—C₁₈ saturated aliphatic carboxylic acids;

(c) dissolved in the said blend of polyethylene glycols, from 10 to 30%, by weight, of a blend of non-ionic surfactants selected from poly(oxoethylene) polyol esters, poly(oxoethylene) polyol ethers and mixtures thereof, the said blend having a weight-average HLB value of at least 14; and

(d) from 0 to 20%, by weight, of glycerin dissolved in the said blend of polyoxyethylene glycols.

7. A suppository as claimed in any of claims 1 to 6 further comprising an effective amount of an antioxidant.

8. A solid, pre-coital, vaginal lubricant suppository as claimed in claim 1 which melts at 37°C, the said suppository having been cast and solidified from a generally homogeneous melt mass comprising:

a continuous phase consisting essentially of:

(a) from 50 to 70%, by weight, based on the weight of the suppository, of a blend of glycols consisting essentially of:

(1) a polyoxyethylene glycol having an average molecular weight of from 900 to 1100; and

(2) a polyoxyethylene glycol having an average molecular weight of from 1200 to 1700, the ration of glycol (2) to glycol (1) being from 1:1 to 4:1;

(b) from 5 to 20%, by weight, based on the weight of the suppository, of glycerin;

(c) from 10 to 30%, by weight, based on the weight of the suppository, of a combination of non-ionic surfactants having a weighted-average HLB value of from 14 to 18, the said combination comprising polyoxyethylene lauryl ether and polyoxyethylene stearate; and

(d) as a discontinuous phase emulsified in and distributed uniformly throughout the said continuous phase, a triglyceride of coconut origin containing caprylic and capric acid residues.

9. A suppository as claimed in claim 8 comprising:

50%, by weight, of the said glycol blend,

20%, by weight, of the said triglyceride,

10%, by weight, of glycerin,

from 10 to 15%, by weight, of a polyoxyethylene lauryl ether having an HLB value of from 16.5 to 17,

from 0 to 5%, by weight, of a polyoxyethylene sorbitan mono-oleate having an HLB value of about 15,

from 5 to 10%, by weight, of a polyoxyethylene stearate having an HLB value of from 16.5 to 17 and an effective amount of an alkylated hydroxyaromatic antioxidant.

10. A suppository as claimed in any of claims 1 to 9 substantially as herein described with particular reference to the Example.

11. A process for the production of a lubricating suppository as claimed in any of claims 1 to 10 which is solid at room temperature, but melts at human body temperature which comprises:

(a) melting a blend of solid polyoxyethylene glycols at a temperature above normal ambient temperatures, but below 70°C thereby obtaining a homogeneous melt;

(b) dissolving in the melt from 10 to 60 parts per 100 based on the weight of the said polyoxyethylene glycols, of a non-ionic surfactant having an HLB value of above 12, while maintaining the melt at a temperature above normal ambient temperature;

(c) distributing throughout the resulting melt from 10 to 40 parts per 100 based on the weight of the said polyoxyethylene glycols, a solid glyceride of an aliphatic carboxylic acid, until the said solid glyceride forms a discontinuous phase uniformly distributed through the melt and emulsified in the said melt, while maintaining the resulting emulsified, two-phase melt at a temperature above normal ambient temperature; and

(d) casting portions of the resulting two-phase melt into the form of suppositories and solidifying the thus-cast portions.

12. A process as claimed in claim 11 substantially as herein described with particular reference to the Example.

13. A method for pre-coitally lubricating a human vagina with a liquid lubricant which comprises:

(a) inserting a solid suppository as claimed in any of claims 1 to 10 into the vagina; and

(b) permitting the said suppository to melt within the vagina prior to coitus to form a water-compatible, lubricious liquid coital lubricant.

14. A method as claimed in claim 13 substantially as herein described.

15. A kit which comprises a suppository as claimed in any of claims 1 to 10 and instructions for the use thereof.

Printed for Her Majesty's Stationery Office by The Tweeddale Press Ltd.,
Berwick-upon-Tweed, 1984.
Published at the Patent Office, 25 Southampton Buildings, London
WC2A 1AY, from which copies may be obtained.